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## REMARKS

In response to the office action mailed October 3, 2003, the present application has been carefully reviewed and amended. Entry of the present amendment and reconsideration of the application are respectfully requested.

Rejections under 35 U.S.C. §112

Claim 30 was rejected for insufficient antecedent basis. Claim 30 has been amended and is believed to comply with 35 U.S.C. §112.

Rejections under 35 U.S.C. §102

*Claims 1-4, 5, 6, 7, 9, and 15*

Claims 1-4, 5, 6, 7, 9, and 15 stand rejected under 35 U.S.C. §102(b) as being anticipated by Cheerios (recipes from Heart Healthy). [Paper 20030929, page 2].

The examiner asserts the composition of Cheerios "is considered to contain homogenized blend of cereal product particulates and milk, because the ingredients are blended in a blender, which would have broken up the cereal pieces into particulates and also homogenized the mixture." [Paper 20030929]

The entire relevant disclosure of Cheerios is:

**Cereal and Milk Shake**

**Ingredients**
**1 cup skim milk**
**1/2 cup Cheerios® cereal**
**1/2 banana**
**1 to 2 tablespoons sugar**

**Directions**
**Place all ingredients in blender.**

**Cover and blend on high speed 10 seconds; scrape sides.**

**Cover and blend about 20 seconds longer or until smooth.**

There is no disclosure of the milk and Cheerios cereal mixture being *homogenized.* The only basis for the Cheerios reference disclosing homogenization is the

examiner's assertion "because the ingredients are blended in a blender, which would have ... homogenized the mixture." [Paper 20030929, page 2]

Blending in a blender is not homogenization. As set forth in the attached industry literature, homogenization is a mechanical treatment of the fat globules and milk brought about by passing milk under high pressure through a tiny orifice, which results in a decrease in the average diameter and an increase in number and surface area of the fat globules. The net result, from a practical view, is a much reduced tendency for creaming (agglomerating) of fat globules.



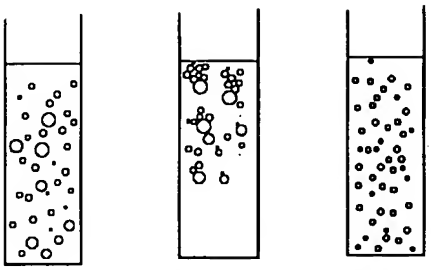
# Homogenization of Milk and Milk Products

The following topics will be covered in this section:

- Introduction
- Homogenization Mechanism
  - turbulence
  - cavitation
- Effect Of Homogenization
  - fat globule properties
  - surface layers

## Introduction

Milk is an oil-in-water ***emulsion***, with the fat globules dispersed in a continuous skimmilk phase. If raw milk were left to stand, however, the fat would rise and form a cream layer. Homogenization is a mechanical treatment of the fat globules in milk brought about by passing milk under high pressure through a tiny orifice, which results in a decrease in the average diameter and an increase in number and surface area, of the fat globules. The net result, from a practical view, is a much reduced tendency for creaming of fat globules. Three factors contribute to this enhanced stability of homogenized milk: a decrease in the mean diameter of the fat globules (a factor in Stokes Law), a decrease in the size distribution of the fat globules (causing the speed of rise to be similar for the majority of globules such that they don't tend to cluster during creaming), and an increase in density of the globules (bringing them closer to the continuous phase) oweing to the adsorption of a protein membrane. In addition, heat pasteurization breaks down the cryo-globulin complex, which tends to cluster fat globules causing them to rise.



Raw milk | Cold, raw milk after 1 hour | Homogenized milk during storage

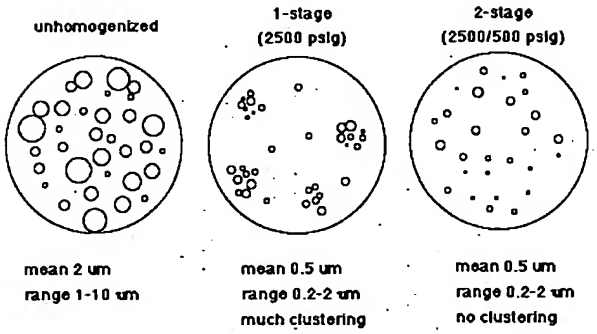
## Homogenization Mechanism

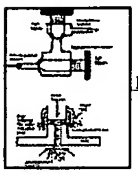
Auguste Gaulin's patent in 1899 consisted of a 3 piston pump in which product was forced through one or more hair like tubes under pressure. It was discovered that the size of fat globules produced were 500 to 600 times smaller than tubes. There have been over 100 patents since, all designed to produce smaller average particle size with expenditure of as little energy as possible. The homogenizer consists of a 3 cylinder positive piston pump (operates similar to car engine) and homogenizing valve. The pump is turned by electric motor through connecting rods and crankshaft.

To understand the mechanism, consider a conventional homogenizing valve processing an emulsion such as milk at a flow rate of 20,000 l/hr. at 14 MPa (2100 psig). As it first enters the valve, liquid velocity is about 4 to 6 m/s. It then moves into the gap between the valve and the valve seat and its velocity is increased to 120 meter/sec in about 0.2 millisec. The liquid then moves across the face of the valve seat (the land) and exits in about 50 microsec. The homogenization phenomena is completed before the fluid leaves the area between the valve and the seat, and therefore emulsification is initiated and completed in less than 50 microsec. The whole process occurs between 2 pieces of steel in a steel valve assembly. The product may then pass through a second stage valve similar to the first stage. While most of the fat globule reduction takes place in the first stage, there is a tendency for clumping or clustering of the reduced fat globules. The second stage valve

permits the separation of those clusters into individual fat globules.

**The Effects of 2-stage Homogenization on Fat Globule Size Distribution as Seen Under the Light Microscope**



Homogenizer and Valve 17 KB

It is most likely that a combination of two theories, turbulence and cavitation, explains the reduction in size of the fat globules during the homogenization process.

**Turbulence**

Energy, dissipating in the liquid going through the homogenizer valve, generates intense turbulent eddies of the same size as the average globule diameter. Globules are thus torn apart by these eddie currents reducing their average size.

**Cavitation**

Considerable pressure drop with charge of velocity of fluid. Liquid cavitates because its vapor pressure is attained. Cavitation generates further eddies that would produce disruption of the fat globules.

The high velocity gives liquid a high kinetic energy which is disrupted in a very short period of time. Increased pressure increases velocity. Dissipation of this energy leads to a high energy density (energy per volume and time). Resulting diameter is a function of energy density.

In summary, the homogenization variables are:

- type of valve
- pressure
- single or two-stage
- fat content
- surfactant type and content
- viscosity
- temperature

Also to be considered are the droplet diameter (the smaller, the more difficult to disrupt), and the log diameter which decreases linearly with log P and levels off at high pressures.

**Effect of Homogenization:**





**Fat globule**

| | No Homogenization | 15 MPa (2500 psig) |
|---|---|---|
| Av. diam. ($\mu$ m) | 3.3 | 0.4 |
| Max. diam. ($\mu$ m) | 10 | 2 |
| Surf. area ($m^2$/ml of milk) | 0.08 | 0.75 |
| Number of globules ($\mu$ $m^{-3}$) | 0.02 | 12. |

**Surface layer**

The milk fat globule has a native membrane, picked up at the time of secretion, made of amphiphilic molecules with both hydrophilic and hydrophobic sections. This membrane lowers the interfacial tension resulting in a more stable emulsion. During homogenization, there is a tremendous increase in surface area and the native milk fat globule membrane (MFGM) is lost. However, there are many amphiphilic molecules present from the milk plasma that readily adsorb: casein micelles (partly spread) and whey proteins. The interfacial tension of raw milk is 1-2 mN/m, immediately after homogenization it is unstable at 15 mN/m, and shortly becomes stable (3-4 mN/m) as a result of the adsorption of protein. The transport of proteins is not by diffusion but mainly by convection. Rapid coverage is achieved in less than 10 sec but is subject to some rearrangement.

**Surface excess** is a measure of how much protein is adsorbed; for example 10 $mg/m^2$ translates to a thickness of adsorbed layer of approximately 15 nm.

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Each of Claims 1-4, 5, 6, 7, 9, and 15 recite in part "a homogenized blend of cereal product particulates and milk."

"Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. *Carella v. Starlight Archery and Pro Line Co.,* 804 F.2d 135, 138, 231 USPQ 644, 646 (Fed. Cir. 1986); *RCA Corp. v. Applied Digital Data Systems, Inc.,* 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic & Research Foundation v. Genentech Inc.,* 18 USPQ2d 1001, 1010 (Fed. Cir. 1991).

The cited reference does not disclose homogenization. The unsupported assertion by the examiner cannot provide the required disclosure. Therefore, the asserted rejection under §102 in view of the Cheerios article cannot be sustained.

*Claims 1-17 and 19*

Claims 1-17 and 19 stand rejected under 35 U.S.C. §102(b) as being anticipated by Dulebohn et al. (WO 00/47063). [Paper 20030929, page 3].

The examiner asserts Dulebohn discloses "a composition containing milk, juice and polysaccharides or stabilizers such as xanthan, carrageenan, alginate or pectin, and cereal such as rice cereal which is pasteurized as in claims 1, 2, 3, 4, 8, 10, 11, 12, 16". [Paper 20030929, page 3] "The mixture is seen to have been homogenized as it is stirred in a blender as in claim 5 and is seen to be stable as it contains the claimed ingredients (page 7, lines 1-5)." [Paper 20030929, page 3].

The cited section of Dulebohn recites:

> **150 mesh. One can also use raw rice, corn, wheat, or oat grain in the same mesh size. The percentage of rice cereal is from 3% to 30%. Stir in the blender for a few seconds; then change the setting to liquefy, and liquefy the mixture for about one minute. Pasteurize the samples**

Claims 1-9 each recite in part "a homogenized blend of cereal product particulates and milk." Dulebohn discloses stirring and liquefying in a blender, but not

homogenization. The lack of at least the "homogenized" limitation precludes the asserted rejection. The unsupported interpretation of homogenization as stirring and/or liquefying cannot sustain the asserted rejection under 35 U.S.C. §102.

Claims 10-17 and 19 each recite in part "a homogenized blend of cereal product particulates, a food stabilizer and a liquid carrier." The stirring or liquefying in a blender of Dulebohn does not disclose the recited homogenized blend. The lack of at least this limitation precludes Dulebohn from sustaining the asserted rejection.

Rejections under 35 U.S.C. §103

*Claims 18-35*

Claims 18-35 stand rejected under 35 U.S.C. §103 has been anticipated by Cheerios or Dulebohn or Dulebohn in view of Cheerios. [Paper 20030929, page 4].

*Claims 18 and 19*

Claims 18 and 19 depend from independent Claim 10 and recite in part "a homogenized blend of cereal product particulates, a food stabilizer and a liquid carrier ...."

As the examiner is aware, "most if not all inventions arise from a combination of all the elements. Thus, every element of a claimed invention may often be found in the prior art. However, identification in the prior art of each individual part claimed is insufficient to defeat patentability to a whole claimed invention . . . there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant." *In re Kotzab*, 217 F.3d 1365, 55 U.S.P.Q. 2d 1313, 1316 [Fed. Cir. 2000]. The Court has stated that "our case law makes clear that the best defense against hindsight based obviousness analysis is the rigorous application of the requirement for showing of teaching or motivation to combine the prior references. Combining prior art references without evidence of such suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability -- the essence of hindsight." *Ecolochem v. Southern California Edison Co.*, 56 U.S.P.Q. 2d, 1065, 1073 (Fed. Cir. 2000)

This court explained in *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697, that "deficiencies of the cited references cannot be remedied by the Board's general conclusions about what is `basic knowledge' or `common sense.'" *In re Lee*, 61 USPQ2d 1430, 1435 (Fed. Cir. 2002).

Neither reference alone, nor in combination, discloses nor suggests the recited "homogenized blend." As set forth by the Federal Circuit, bare assertions cannot take the place of objective evidence. Therefore, applicants respectfully submit the outstanding rejection of Claims 18 and 19 cannot be sustained.

*Claims 20-29*

Claims 20-29 recite in part "a container having a user operable closure mechanism; and ... a homogenized blend of a particulated cereal product, a stabilizer and milk in the container."

None of the cited references disclose or suggest a homogenized blend of particulated cereal product, a stabilizer and milk. Therefore, Claims 20-29 are in condition for allowance.

*Claims 30-32*

Claims 30-32 recite in part "homogenizing the cereal particles, stabilizer and milk."

As none of the cited references disclose or suggest the homogenization of cereal particles, stabilizer and milk, these claims are in condition for allowance.

The examiner also asserts it would have been obvious to use the polysaccharides of Dulebohn in place of the SUCRELESSE of Dulebohn because they perform the same function of stabilizing the mixture and either is disclosed as being a stabilizer. [Paper 20030929, page 5]

However, Dulebohn expressly employs SUCRELESSE to stabilize milk proteins and prevent the proteins from precipitating in the presence of the acidic juice. [Dulebohn, page 4, line 27, through page 5, line 1]. SUCRELESSE is an amino acid, organic (or inorganic) acid and metal ion composition, specifically employed to stabilize

milk proteins in the emulsion of milk, juice, and grain/polysaccharide. [Dulebohn, page 4, lines 20-23]

There is no basis for the assertion that a polysaccharide would bind the milk proteins in the acid environment. Therefore, the lack of any suggestion precludes Dulebohn from sustaining the asserted rejection.

*Claims 33-35*

Claims 33-35 recite in part "A food product mix for forming a drink composition, comprising:

(a) a particulated toasted cereal product, the particulates having an average size less than [[100]] 60 microns; and

(b) a food stabilizer. "

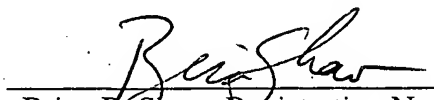
The examiner asserts Dulebohn discloses that "sieve screens can be between 60 150 mesh which is 250 microns to 106 microns i.e. a 140 mesh screen. Certainly, a 150 mesh screen would have been about 100 microns. Nothing new is seen as in claim 35 in the use of a dehydrated milk product if one wanted to make a dry mix as non-fat dry milk is commonly substituted for liquid milk. Therefore, it would have been obvious to use a toasted cereal as disclosed by Cheerios for the cereals of Deleon [sic Dulebohn] and to use known ingredients in the claimed micron size as disclosed above." [Paper 20030929, pages 5-6]

However, the examiner has failed to account for the explicit teachings of Dulebohn in which the particle sizes range from 60 to 150 mesh (250 microns to 106 microns). The present claim is currently opposite to the recited range relied upon by the examiner. That is, the range of the prior art extends upward; in contrast, the recited range of the claim defines the opposite smaller particle sizes. In addition, the related food stabilizer is contrary to the protein binder SUCRELESSE in Dulebohn.

Further, there is no support in the art of record that the amino acid based SUCRELESSE for binding milk proteins to reduce precipitation is a food stabilizer as recited in the claims.

Therefore, applicants respectfully submit all the pending claims, Claims 1-35, are in condition for allowance; and such action is earnestly solicited. If, however, the examiner feels any further issues remain, the examiner is cordially invited to contact the undersigned so that such matters can be promptly resolved.

Respectfully submitted,



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